Making an SOP System Effective as a Learning Tool
Assumptions and Checklist

In the sciences, ongoing learning is essential. A key area to maximize learning is through a well-developed SOP system. After reviewing thousands of SOPs, there are common weaknesses I have observed in company SOP systems that reduce their effectiveness as training (learning) tools. Following is a set of general assumptions I believe need to be made when developing a set of SOPs that are intended to say what you do in a manner that effectively teaches. After the set of assumptions, a checklist that you could use in evaluating an SOP system's effectiveness as a training (learning) tool is provided.

Assumptions

Learning
- The trainee may speak English as a second language.
- Some people learn better through text, some with pictures, and some with both.
- If a trainee can ask a question from a good scientific perspective, it is a good question that should be addressed.
- A regulatory agency inspector, or an auditor, will likely know no more than a typical trainee about the SOP, and thus the SOP system should serve to answer their questions as well as a trainee's.

Linkages
- The trainee may not necessarily know where to go in a documentation system to find answers.
- The trainee may want to understand a method derived from external sources (e.g. USP, EP, ASTM, etc.) and its underlying principle.
- The SOP system should contain references to all necessary/associated internal/ external documents.
- The trainee may not know terms that are understood by the SOP author.
- The SOP system should be internally consistent.
- Terms should be used consistently within and across SOPs.

SOP Specifics
- Analytical measurements will not be 100% accurate.
- Accuracy and precision requirements should be appropriate.
- The purpose of the SOP should be clear, as should its scope.
- The text of the SOP should be accurate, with no typos.
- The materials and equipment needed for the SOP should be comprehensively listed.
- It must be clear how and where to record results.

Checklist

The following checklist items may be useful when evaluating an SOP system, but certainly should not be considered all inclusive.

Learning

Pictures are used wherever appropriate to improve learning by reducing text and ambiguity.

☐ good ☐ needs improvement

Pictures are well labeled.

☐ good ☐ needs improvement

A trainee, or even an experienced technician may ask good questions at any time. A regulatory inspector/other auditor may have the same or similar questions. Some of these may be anticipated by having the SOP reviewed by someone who is not intimately familiar with the procedure. Was the SOP reviewed by such a person or persons?

☐ good ☐ needs improvement

Linkages

Common terms such as analytical balance, DI water, etc. are defined either within the SOP or within a referenced common definitions document. These terms should be used consistently.

☐ good ☐ needs improvement

The SOP system should be internally consistent. For example, many systems include at least one SOP on SOPs. Is the format as described in this SOP applied consistently across all SOPs? If there is more than one format for SOPs, are the different formats derived from the root SOP on SOPs, and is the chain of references comprehensive?

☐ good ☐ needs improvement

All appropriate internal document references should be contained within the SOP. For example, if an analytical SOP indicates the usage of a pH meter, there should be a reference to the SOP that explains how to do this.

☐ good ☐ needs improvement

All appropriate external document references should be contained within the SOP. For example, if an analytical SOP indicates the usage of a method found in the USP, there should be a reference to the section of the USP containing that method. Also references to operating manuals, etc. should be provided.

☐ good ☐ needs improvement

The SOP system should contain no unlinked documents. In some manner or another, all SOPs need to be linked together, and the linkages need to be unambiguous. If a document is called "XYZ" at one place in the system, calling the same document "ZYX" in other places will only lead to confusion. Such consistent linkages facilitate the job of

learning for the trainee as well as ready comprehension of the SOP system by regulatory inspectors/other auditors.

☐ good   ☐ needs improvement

The SOP system should not have any "orphan" documents. For example, a log sheet or data sheet should not be found in the system without clear linkages to other parts of the system.

☐ good   ☐ needs improvement

The SOP should not include separate documents with the same SOP number.

☐ good   ☐ needs improvement

The SOP revision history should be clear, easy to trace, with no unexplained gaps.

☐ good   ☐ needs improvement

SOP Specifics
The SOP should not have any typos.

☐ good   ☐ needs improvement

The SOP title should be consistent with the rest of the document.

☐ good   ☐ needs improvement

The SOP should clearly state its purpose. For example, if the SOP covers a qualitative procedure, it should not include quantitative results as well. The SOP should state where the requirements come from if it is intended to address whether an article under test meets these requirements.

☐ good   ☐ needs improvement

The SOP should clearly state its scope. For example, if the SOP system includes methods for measuring the viscosity of an assortment of materials, the scope must make it clear what materials the specific SOP is to be used with.

☐ good   ☐ needs improvement

The SOP should clearly state all materials and equipment needed for its proper execution. Additional required materials/equipment should not appear in other portions of the SOP without having been listed in the required materials and equipment section(s).

☐ good   ☐ needs improvement

The SOP should clearly state what is to be done and where results are to be recorded. If several alternative methods are included in a single SOP, it should be unambiguous as to which to use.

☐ good   ☐ needs improvement

The SOP should clearly state what is to be done if the results are not as expected. The SOP should not say to do a retest without scientific justification.

☐ good   ☐ needs improvement

The SOP should clearly state where to record related information such as logbook data, calibration data, etc. Ambiguity is not to exist.
☐ good   ☐ needs improvement

The SOP procedure should use validated methods. These may be derived from external methods (ASTM, USP, others) or internal method development and validation. Also see the Linkages section of this checklist.
☐ good   ☐ needs improvement

The SOP should use appropriate analytical ranges. For example, if the SOP states to stir at 25C for 10 minutes, does this mean exactly 25C for exactly 10 minutes? 24.5 to 25.4C for 9.5 to 10.4 minutes? Ambiguity must be eliminated. Also, if it really doesn't matter that a weighed amount be exactly 23.0034 g (for example), and what really matters is that the amount be between 22 and 24 g, indicate as much (23 +/1 g).
☐ good   ☐ needs improvement

Materials listed that are trade names should be clearly identified as such.
☐ good   ☐ needs improvement

The SOP should not include superfluous information.
☐ good   ☐ needs improvement

The SOP should avoid unnecessary specificity. For example, citing to a specific volume of the USP should be replaced with a citation to the "current USP".
☐ good   ☐ needs improvement

The SOP should not include colloquial terms. For example, the term "quats" should be spelled out, as there are other meanings then the intended chemical one.
☐ good   ☐ needs improvement

The SOP should fully address safety issues.
☐ good   ☐ needs improvement

The SOP should not include attachments/appendices that are not referenced from with the body of the SOP.
☐ good   ☐ needs improvement

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